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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,751	04/24/2006	Daria Onichtchouk	WIECKM-52	9861

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

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06/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,751	ONICHTCHOUK, DARIA	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 37-58 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 37, 47, 55 and 58, drawn to a pharmaceutical composition comprising a DG008, DG065, DG210 or DG239 protein and/or a functional fragment thereof; and first method of use using the same composition along with a kit comprising the same.

Group 2, claims 37-47, 54 and 58, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a DG008, DG065, DG210 or DG239 protein and/or a functional fragment thereof; and first method of use using the same composition along with a kit comprising the same.

Group 3, claims 37, 47 and 58, drawn to a pharmaceutical composition comprising an effector/modulator of DG008, DG065, DG210 or DG239 protein and/or a functional fragment thereof (e.g., antibodies; see instant specification at least page 21); and first method of use using the same composition along with a kit comprising the same.

Group 4, claims 37, 47 and 58, drawn to a pharmaceutical composition comprising an effector/modulator of a nucleic acid encoding DG008, DG065, DG210 or DG239 protein and/or a functional fragment thereof (e.g., antisense molecules, aptamers, RNAi molecules or ribozymes; see instant specification at least on page 22, last paragraph); and first method of use using the same composition along with a kit comprising the same.

Group 5, claim 48, drawn to a method for identifying substances capable of interacting with a DG008, DG0065, DG210 or DG239 polypeptide using DG008, DG065, DG210 or DG239 nucleic acid molecule or a fragment or a variant thereof.

Group 6, claim 48, drawn to a method for identifying substances capable of interacting with a DG008, DG0065, DG210 or DG239 polypeptide using an effector/modulator of DG008, DG065, DG210 or DG239 protein or a fragment or a variant thereof.

Group 7, claim 48, drawn to a method for identifying substances capable of interacting with a DG008, DG0065, DG210 or DG239 polypeptide using an effector/modulator of DG008, DG065, DG210 or DG239 nucleic acid molecule or a fragment or a variant thereof.

Group 8, claims 49 and 57, drawn to a non-human transgenic animal exhibiting an increased expression of a DG008, DG065, DG210 or DG239 polypeptide; and a method for the production of the same.

Group 9, claims 49 and 57, drawn to a non-human transgenic animal exhibiting a reduced expression of a DG008, DG065, DG210 or DG239 polypeptide; and a method for the production of the same.

Group 10, claims 50, 56 and 58, drawn to a recombinant host cell exhibiting a modified expression of a DG008, DG065, DG210 or DG239 polypeptide which comprises a nucleic acid molecule of the present invention; and the first method of using the same for the preparation of a medicament along with a kit comprising the same.

Group 11, claims 48 and 51, drawn to a method of identifying a polypeptide involved in the regulation of energy homeostasis and/or metabolism in a mammal using DG008, DG0065, DG210 or DG239 polypeptide.

Group 12, claim 52, drawn to a method of screening for an agent which **effects/modulates the interaction of a DG008, DG065, DG210 or DG239 polypeptide** with a binding target.

Group 13, claim 53, drawn to a method of screening for an agent which **effects/modulates the activity of a DG008, DG065, DG210 or DG239 polypeptide** with a binding target.

The currently claimed subject matter (Inventions of Groups 1-14) lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The compositions in Groups 1-4 and 8-10 differ one from the others because they are structurally, physically and chemically different one from the others, as well as different properties. For example, the pharmaceutical composition of Group 1 is made up of amino acids; the pharmaceutical composition of Group 2 is composed of nucleotides; the pharmaceutical composition of Group 3 is directed to an effector/modulator of DG008, DG065, DG210 or DG239 protein or functional fragment thereof, such as antibodies which clearly have different properties and structures from those of DG008, DG065, DG210 or DG239 protein; the pharmaceutical composition of Group 4 is drawn to an effector/modulator of a nucleic acid encoding DG008, DG065, DG210 or DG239 protein of a fragment thereof such as antisense molecules, aptamers, RNAi molecules or ribozymes which are clearly different in structures and properties from DG008, DG065, DG210 or DG239 nucleic acids. The non-human transgenic animals in Groups 8-9 are living entities that are physically different from other compositions, and that these non-human transgenic animals in Groups 8-9 have mutual exclusive properties (increased vs reduced expression of a DG008, DG065, DG210 or DG239 protein). Similarly, the recombinant host cell exhibiting modified expression of a DG008, DG065, DG210 or DG239 protein in Group 10 are physically and structurally different from the above mentioned compositions.

The methods in Groups 5-7 and 11-13 do not share the same technical feature because each method differs from the others in the starting materials and different method steps. Additionally, none of the methods in Groups 5-7 and 11-13 requires any of the compositions in Groups 1-4 and 8-10.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A. Additionally, should Applicants elect anyone of Groups 1-13, Applicants are further required to elect one of the followings:

(i) DG008 (SPAC-like 1 or hevin),

(ii) DG0065 (human SPARC related modular calcium binding 2),

(iii) DG210 (secreted Frizzled-related protein 1 or SFRP1),

(iv) DG239 (human granulin precursor),

This is an additional group restriction, because DG008, DG0065, DG210 and DG239 lack unity of invention because each represents a different gene that is different structurally and functionally one from the others.

B. Should Applicants elect anyone of Groups 4 and 7; Applicants are further required to elect a specific effector/modulator of DG008, DG0065, DG210 or DG239 nucleic acid or a fragment or variant thereof from the followings:

(i) anti-sense oligonucleotide,

(ii) an aptamer,

(iii) RNAi molecule,

(iv) ribozyme,

This is an additional group restriction, because each of the above effector/modulators lack unity of invention one from the others because they are different structurally, chemically one from the others as well as different properties.

Additionally, it has also been decided that, due to the high burden on the Office to search sequences ONE sequence constitutes a reasonable number for examination purposes. Examination will be restricted to only the one elected sequence within each elected Group. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (e.g., oligomeric probes and/or primers).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN, Ph.D./
Primary Examiner, Art Unit 1633